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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/600,055	06/20/2003	Uwe Ries	1/1358	5854

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EXAMINER	
WANG, SHENGJUN	
ART UNIT	**PAPER NUMBER**
1617	

DATE MAILED: 10/04/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/600,055	RIES ET AL.	
	Examiner	Art Unit	
	Shengjun Wang	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *17 July 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-19* is/are pending in the application.

4a) Of the above claim(s) *7-10 and 13-19* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-6,11 and 12* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Claims 15-19 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, claims 7-10, 13-14 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected species, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on July 17, 2006.

2. Applicant's election without traverse of invention group I, and compound of formula IIa, and physiological activators and inhibitors of the clotting systems and their recombinant analogues of claim 11 in the reply filed on July 17, 2006 is acknowledged.

Claim Objection

3. Claim 1 is objected to because of the following informalities: claim 1 line 3 "bacteranemia" appears to be a typographic error for "bacteraemia." Appropriate correction is required.

Claim Rejections 35 U.S.C112

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 11 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claim recites "physiological activators and inhibitors of the clotting system and their recombinant analogues." The application fails to provide a proper written description commensurate in scope for "physiological activators and inhibitors of the clotting system and their recombinant analogues." The application provide three lines description for "physiological activators and inhibitors of the clotting system and their recombinant analogues" by merely giving the few examples, and provide no further information as to the structures, properties and means for obtaining those materials. The application provide neither the material structure of the supposed "physiological activators and inhibitors of the clotting system and their recombinant analogues", no written description of their utilities in increasing in treatment and prevention of SIRS, sepsis, and bacteraemia. Attention is directed to *General Electric Company v. Wabash Appliance Corporation et al* 37 USPQ 466 (US 1938), at 469, speaking to functional language at the point of novelty as herein employed: the vice of a functional claim exists not only when a claims is wholly functional, if that is ever true, but when the inventor is painstaking when he recites what has already been seen, and then uses conveniently functional language at the exact point of novelty. Functional language at the point of novelty, as herein employed by Applicants, is further admonished in *University of California v. Eli Lilly and Co.* 43 USPQ2d 1398 (CAFC 1997) at 1406: stating this usage does little more than outlin[e] goals appellants hope the recited invention achieves and the problems the invention will hopefully ameliorate. Applicants functional language at the point of novelty fails to meet the requirements set forth under 35 USC 112, first paragraph. Claims employing functional language at the point of novelty, such as Applicants, neither provide those elements required to practice the inventions, nor inform the public during the life of the patent of the limits of the monopoly asserted *General Electric*

Company v. Wabash Appliance Corporation et supra, at 468. By reading the specification herein, the skilled artisan cannot envision the detailed chemical structure of the encompassed genus of "physiological activators and inhibitors of the clotting system and their recombinant analogues." Further, description of what a compound can do, in steed of what the compound actually is, is not a proper written description for that compound.

5. Claims 1-6, 11 and 12 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for treatment of SIRS, sepsis and bacteraemia, does not reasonably provide enablement for prevention of such disorders. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims. The instant specification fails to provide information that would allow the skilled artisan to practice the instant invention without undue experimentation. Attention is directed to In re Wands, 8 USPQ 2d 1400 (CAFC 1988) at 1404 where the court set forth the eight factor to consider when assessing if a disclosure would have required undue experimentation. Citing Ex parte Forman, 230 USPQ 546 (BdApls 1986) at 547 the court recited eight factors:

1) the quantity of experimentation necessary,

2) the amount of direction or guidance provided,

3) the presence of absence of working examples,

4) the nature of the invention,

5) the state of the prior art,

6) the relative skill of those in the art,

7) the predictability of the art, and

8) the breadth of the claims.

The claim recites the prevention of systemic inflammatory response syndrome (SIRS), sepsis, and bacteraemia. SIRS, sepsis in particular, may arise from distinct etiologies. See, e.g., paragraphs 4-11 in Saint-Remy. The application discloses the particular anti-thrombin agent is effective in suppressing the formation of thrombin-antithrombin (TAT complex) and thereby suppressing the development of sepsis. See, pages 37-40. However, the application fails to articulate how these method would be effective for preventing the occurs of systemic inflammatory response syndrome, sepsis in particular. In fact, even applicants are not so convinced that the method would actually be effective in preventing such disorders. "Accordingly the invention relates to a process for the treatment or *possibly also* the prevention of diseases subsumed under the heading SIRS..." (emphasis added). page 28, lines 15-17 of the application. The pharmaceutical art is unpredictable, requiring each embodiment to be individually assessed of physiological activity. The specification nor the prior art of record (WO 00/01704) provide any guidance for one of skill in the art to use the invention in expectation of administering a therapeutically effective amount of antithrombotic agent herein for prevention SIRS, in general or sepsis in particular. Although one would like to prevent SIRS, or sepsis, numerous factors are associated with causing SIRS, or sepsis (see, particularly, paragraph 4 and 8 in Saint-Remy et al.(US 2003/0175268 A1), such that the prior art and the instant specification fail to enable the prevention of SIRS, sepsis, bacteraemia, but do enable treatment of such disorders. It is noted that the pharmaceutical art generally is unpredictable, requiring each embodiment to be individually assessed for physiological activity, The court in In re Fisher, 427 F.2d 833, 839; 166 USPQ 18, 24 (CCPA 1970) held that, "in case involving unpredictable

factors, such as most chemical reactions and physiological activity, the scope of enablement obviously varies inversely with the degree of unpredictability of the factors involved." The more unpredictable an area, the more specific enablement is need in order to satisfy the statue. The Unpredictability is more apparent where the diseases disclosed in the specification are as complex and diverse in etiology and patient populations as the many types and causes for SIRS, sepsis, bacteraemia. In the instant case, that art does have product available for treatment of patients presenting with SIRS, sepsis, and bacteraemia, but the art and the evidence presented in the instant application fails to establish support for prevention, as instantly claimed. Thus it would require undue experimentation for the skilled artisan to practice the invention as broadly claimed.

Claim Rejections 35 U.S.C. 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

7. Claims 1-6, 11 and 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ries et al. (WO00/01704, IDS), in view of Romisch et al. (EP 1 027 894), Tsukada et al. (EP 0 781 558) and Iqbal et al. and in further view of Merck Manual regarding bacteraemia.

Ries et al. teaches that the compounds herein, encompassing the elected compound, are known as antithrombotic pharmaceutical agents. See, particularly, the abstract, the examples, and the

claims. Ries et al. do not teach expressly the employment of the antithrombotic agent for treating sepsis, or related disorders, bacteraemia.

However, Romisch et al. Tsukada et al. and Iqbal et al. disclosed that antithrombotic agent s have been known as useful for treatment of sepsis. See, particularly, the abstracts and the claims of both Tsukada et al. and Romisch et al. and the abstract of Iqbal et al. Sepsis, is an stage of Systemic inflammatory responsive syndrome, and often arise from bacteraemia (Merck Manual). Microvascular thrombosis and disseminated intravascular coagulation are the common symptoms fro sepsis. See, columns 1-2 in Romisch et al. and pages 111-115 of Iqbal et al. It is also known in the art that anticoagulants agent, including those of antithrombotic agents are expected to be useful for treating sepsis. See, page 118 and 119 in Iqbal et al.

Therefore, it would have been prima facie obvious to a person of ordinary skill in the art, at the time the claimed the invention was made, to employ the compound herein for the treatment or prophylactic treatment of sepsis, including for those patients suffering from bacteraemia.

A person of ordinary skill in the art would have been motivated to employ the compound herein for the treatment or prophylactic treatment of sepsis, including for those patients suffering from bacteraemia because antithrombotic agents are known to be useful for treatment of sepsis.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shengjun Wang whose telephone number is (571) 272-0632. The examiner can normally be reached on Monday to Friday from 7:00 am to 3:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan, can be reached on (571) 272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

SHENGJUN WANG
PRIMARY EXAMINER

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Primary Examiner
Art Unit 1617